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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,434	08/19/2003	Jen Sheen	00786/366003	4423

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BOSTON, MA 02110

EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/643,434	Applicant(s) SHEEN ET AL.	
	Examiner Medina A. Ibrahim	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 08/11/05 in reply to the Office action of 02/10/05 has been entered. The sequence listings of 08/11/05 have been entered. Claims 1-5 and 8-11 are amended. Therefore, claims 1-14 are pending and are examined.

This Office action contains NEW GROUNDS OF REJECTIONS not necessitated by Applicant's amendments. Therefore, this action is non-final. The delay in applying these grounds of rejection is regretted.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment and/or upon further consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic plant/cell comprising a recombinant nucleic acid encoding the plant MAPKKK polypeptide of SEQ ID NO: 7, 9, 11, 15 or 19, a vector comprising said nucleic acid operably linked to promoter functional in plant cells, does not reasonably provide enablement for a plant transformed with a recombinant nucleic acid encoding any constitutively active MAPKKK including those

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from animals and fungi or kinase domains thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to plants comprising a recombinant nucleic acid encoding a polypeptide comprising a constitutively active kinase domain of a MAPKKK or a kinase domain thereof, said nucleic acid is expressed in said plant under the control of a promoter functional in a plant cell. The claims are also drawn to transformed monocot and dicot plants and a vector comprising said nucleic acid under the control of said promoter, and plant cell comprising said vector. The claims are further drawn to said plants wherein the nucleic acid is from fungi or animal. In contrast Applicant teaches plants transformed with an expression vector comprising nucleic acid encoding the plant MAPKKK polypeptide of SEQ ID NO: 7, 9, 11, 15 or 19 operably linked to specific promoters functional in plant cells.

Applicant has not taught the obtention and use of all nucleic acids from all natural sources including all animals and fungi encoding a polypeptide comprising a constitutively active kinase domain of MAPKKK or a kinase domain thereof. Applicant has not taught that the constitutive expression of all MAPKKK encoding nucleic acids or the kinase domains thereof would affect plant stress signal transduction pathway. While several MAPKKK genes have been isolated and characterized, the prior art provides limited guidance regarding the specific roles of these MAPKKK in plant stress signal transduction pathways. In the absence of such guidance, undue trial and error experimentation would be required to screen through the myriad of transgenic plants

transformed with each of different nucleic acids encoding a constitutively active kinase of a MAPKKK or kinase domain thereof to determine the phenotypic effect of each of nucleic acids in the transgenic plants.

While transformation of plants with a desired is routine, transformation of plants for specific phenotype is unpredictable. Applicant's own working examples provide evidence that not all nucleic acids encoding MAPKKK or kinase domain can provide predictable phenotypic effect in transgenic plants. On column 18, lines 26-29, Applicant teaches that constitutive expression of either mutated NPK1 kinase domain or the CTR1 kinase domain didn't have any effect on the expression of the dicot reporter genes. At the paragraph bridging columns 18 and 19, Applicant also teaches that while constitutively active ANP1, ANP2, and ANP3 effectively suppressed GH3 promoter induction by auxin, other tested protein kinases didn't have any effect.

Since the working examples disclosed in the specification are limited to the use of the MAPKKK genes of ANPs from tobacco and NPKs of Arabidopsis, the ability of said MAPKKK genes to induce stress resistance in transgenic plants cannot be extrapolated to all MAPKKK encoding nucleic acids or kinase domain thereof including those from all fungi and animals, absent further guidance regarding the role of each of said MAPKKK in plant stress signal transduction pathways, if any.

Therefore, given the limited guidance in the specification and in the prior art regarding roles of MAPKKK encoding nucleic acids and kinase domains thereof in plant stress signal transduction pathways, the broad scope of the claims; the limited working examples, and unpredictability inherent in transforming plants with MAPKKK for a

desired phenotype as evidenced by Applicant's own working examples, the claimed invention cannot be practiced throughout the broad scope without undue experimentation. Therefore, the claims are not enabled. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). See also *In re Fischer*, 166 USPQ 19 24 (CCPA 1970) where the court held the scope of the claims must bear a reasonable correlation with the scope of the enablement.

In *Genentech Inc. v. Novo Nordisk A/S* (42 USPQ2d 1001 at p. 1005) The CAFC stated "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not workable... While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention... [W]hen there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required....".

An amendment to claims 1 and 10 to recite SEQ ID NO: would obviate the above rejection.

Claim Rejections - 35 USC § 102

Claims 1, 4-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanksley et al (US 5, 648, 599, Applicant's IDS). This rejection is repeated for the reasons of record as set forth in the last Office action of 02/10/05. Applicant's arguments filed 08/11/05 have been considered but are not deemed persuasive.

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Applicant argues that Tanksley et al do not teach that *Pto* gene taught is a MAPK, a MAPKK or even a MAPKKK, and that it does not encode a polypeptide with a regulatory domain that can be deleted for constitutive activity as in MAPKKK (response, p. 7).

This is not found persuasive. The claims as amended recite a transgenic plant comprising a recombinant nucleic acid encoding a polypeptide comprising a constitutively active kinase domain of a MAPKKK or a kinase domain thereof. The claims do not require a MAPK, a MAPKK or even limited to MAPKKK. The claims do not recite a specific structural feature that would distinguish the kinase domain of the MAPKKK from the kinase domain of the *Pto* gene. The claims do not recite a specific regulatory domain that can be deleted to render the polypeptide constitutively active. The cited reference teaches that *Pto* nucleic acid encodes a polypeptide comprising the serine/threonine kinase catalytic domain (subdomains VI and VIII) that is believed to be based on gene for gene recognition and is known to be conserved in disease resistance kinase polypeptides from various organisms (columns 19-20; Example 7). Applicant has provided no evidence showing that the serine/threonine kinase polypeptide encoded by the *Pto* nucleic acid is not constitutively activated upon recognition of the invading pathogen gene product. Therefore, Tanksley et al teaches the claimed invention, as stated in the last Office action.

Remarks

Claims 2-3 are free of the prior art of record.

No claim is allowed.

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Contact Information

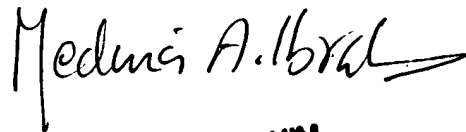
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mai

10/31/05



**MEDINA A. IBRAHIM
PATENT EXAMINER**